IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Robbins *et al.*		
Serial No.	:	10/075,869	Examiner :	P. Ponnaluki
Filed	:	February 13, 2002	Group Art Unit:	1639
For:		IDENTIFICATION OF PEPTIDES THAT FACILITATE UPTAKE AND CYTOPLASMIC AND/OR NUCLEAR TRANSPORT OF PROTEINS, DNA, AND VIRUSES		

RESPONSE TO RESTRICTION REQUIREMENT

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Box 1450, Alexandria, VA 22313-1450.

August 27, 2004
Date of Deposit

Rochelle K. Seide
Attorney Name

32,300
Registration No.

Rochelle K. Seide
Signature

August 27, 2004
Date of Signature

Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

Sir:

This paper is in response to the Office Communication dated July 8, 2004 for the above-identified application. Applicants request a one month extension of time for responding to the Office Action, up through and including September 8, 2004, and enclose a check in payment of the fee under 37 C.F.R. § 1.17(a)(1).

The Examiner has issued a restriction requirement and requires selection of one of 189 groups of claims for prosecution in this application. The Examiner has placed the pending claims into the following groups:

Groups 1-11: Claims 1(in-part), 2, 5, drawn to a peptide having an amino acid sequence of SEQ ID NOS:76, 77, 78, 79, 80, 81, 82, 83, 84, 85, and 86, respectively;

Group 12: Claims 1(in-part), 2, 5, drawn to a peptide having an amino acid sequence of SEQ ID NOS: 97, 98 and 99;

Group 13: Claim 3, drawn to a peptide having an amino acid sequence of SEQ ID NO:59;

Groups 14-24: Claims 6-14, 17, 42, and 45-47(in-part), drawn to a peptide-cargo complex having an amino acid sequence of SEQ ID NOS:76, 77, 78, 79, 80, 81, 82, 83, 84, 85, and 86, respectively, and a cargo, immunogen;

Group 25: Claims 6-14, 17, 42, and 45-47(in-part), drawn to a peptide-cargo complex having an amino acid sequence of SEQ ID NOS: 97, 98 and 99 and a cargo, immunogen;

Group 26: Claim 15, drawn to a peptide-cargo complex having an amino acid sequence of SEQ ID NO:59 and a cargo;

Groups 27-38: Claims 18-24(in-part), drawn to an expression cassette comprising DNA encoding a fusion protein comprising a leader sequence, a protein of interest and an internalizing peptide having an amino acid sequence of SEQ ID NOS: 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, and 86, respectively, and a transfer vector (*group 30 is a repeat of group 29 and should be eliminated; groups should be renumbered 27-37*);

Group 39: Claims 18-24(in-part), drawn to an expression cassette comprising DNA encoding a fusion protein comprising a leader sequence, a protein of interest and an internalizing peptide having an amino acid sequence of SEQ ID NOS: 97, 98, and 99, respectively, and a transfer vector (*group should be renumbered 38*);

Groups 40-50: Claims 25(in-part), and 31-35, drawn to a method of inducing synovial cell death comprising administering a peptide-cargo complex to said tumor cell, and the peptide

has an amino acid sequence of SEQ ID NOS: 77, 78, 79, 80, 81, 82, 83, 84, 85, and 86, respectively (*SEQ ID NO: 76 has been omitted; the groups should be renumbered 39-49*);

Group 51: Claims 25(in-part), and 31-35, drawn to a method of inducing synovial cell death comprising administering a peptide-cargo complex to said tumor cell, and the peptide has an amino acid sequence of SEQ ID NOS: 97-99 (*the group should be renumbered 50*);

Groups 51-61: Claims 26(in-part), 29, and 31-35, drawn to a method of inducing apoptosis in a tumor cell comprising administering a peptide-cargo complex to said tumor cell, and the peptide has an amino acid sequence of SEQ ID NOS: 77, 78, 79, 80, 81, 82, 83, 84, 85, and 86, respectively (*SEQ ID NO: 76 has been omitted*);

Group 62: Claims 26(in-part), 29, and 31-35, method of inducing apoptosis in a tumor cell comprising administering a peptide-cargo complex to said tumor cell, and the peptide has an amino acid sequence of SEQ ID NOS: 97-99;

Groups 63-73: Claims 27(in-part), and 31-35, drawn to a method for reducing white cells in arthritic joints comprising administering a peptide-cargo complex, where the peptide has an amino acid sequence of SEQ ID NOS: 77, 78, 79, 80, 81, 82, 83, 84, 85, and 86, respectively (*SEQ ID NO: 76 has been omitted*);

Group 74: Claims 27(in-part), and 31-35, drawn to a method for reducing white cells in arthritic joints comprising administering a peptide-cargo complex, where the peptide has an amino acid sequence of SEQ ID NOS: 97-99;

Groups 75-152: Claims 28(in-part), and 31-35, drawn to a method for inhibiting apoptosis in an islet cell comprising administering a peptide-cargo complex to said islet cells, wherein the peptide has an amino acid sequence of SEQ ID NOS: 1-18, 25-86, and 97-99 (*the groups should be renumbered 75-155*);

Group 153: Claims 36 and 37, drawn to a method of internalizing peptide-cargo complex into a cell (*the groups should be renumbered 156*);

Groups 154-165: Claims 38-41(in-part), drawn to a method of internalizing peptide-cargo complex into a cell comprising administering a peptide-cargo complex, and a GST-fusion protein, a glutathione as cargo, and the peptide has an amino acid sequence of SEQ ID NOS: 76-86 and 97-99 (*the groups should be renumbered 157-168*);

Groups 166-177: Claims 48-50, drawn to a method for eliciting an immune response in a subject comprising administering an immunogen comprising a peptide-cargo complex, wherein the peptide has an amino acid sequence of SEQ ID NOS: 76-86 and 97-99 (*the groups should be renumbered 169-180*); and

Groups 178-189: Claims 30, 34, and 35, drawn to a method for delivering anti-oxidant and anti-inflammatory agents to lung epithelial cells by administering a peptide-cargo complex, wherein the peptide has an amino acid sequence of SEQ ID NOS: 76-86 and 97-99 (*the groups should be renumbered 181-192*).

The Examiner alleges that Groups 1-13 are distinct, because the inventions are drawn to distinct peptides with different amino acid sequences, are structurally distinct and do not share a common core structure.

The Examiner alleges that groups 14-26 are distinct, because the inventions are drawn to different peptide-cargo complexes, each with a different peptide sequence that is structurally distinct and not capable of use together.

The Examiner alleges that groups 27-39 are distinct, because the inventions are drawn to different expression cassettes, each with a different peptide sequence that is structurally distinct and not capable of use together.

The Examiner alleges that the inventions of groups 1-13 (peptides), 14-26 (peptide-cargo complexes), and 27-39 (expression cassettes) are distinct from each other, not capable of use together, and have different modes of operation, different functions, or different effects.

The Examiner alleges that the inventions of groups 40-189 are drawn to different methods of using different cargo-peptide complexes, not disclosed as capable of use together, and have different modes of operation, different functions, or different effects.

The Examiner has acknowledged that the inventions of group 14-26 (products) and group 40-189 (methods) are related as product and process of use. However, the Examiner alleges that the restriction is proper, because the different products of groups 14-26 can allegedly be used in more than one group of groups 40-189.

With regard to the designation of groups of inventions, Applicants note several errors in the listing of groups and claims thereof. Applicants submit the attached Appendix A, which correctly lists the groups for restriction. First of all, there should be 192 groups, instead of 189 (see Appendix A). Secondly, group 30 is a repeat of group 29 and should be eliminated. Therefore, the Examiner's groups 27-39 should be renumbered as 27-38. With regard to groups 40-50, 51-61, 63-73, the Examiner has omitted groups directed to the subject matter of SEQ ID NO:76. Therefore, these groups should be renumbered accordingly. Group 51 is listed as both drawn to a method of inducing synovial cell death and a method of inducing apoptosis in a tumor cell. With regard to groups 75-152, the Examiner has omitted three groups. Accordingly,

groups 75-152 and 153-189 should be renumbered. Reference to the groups hereinafter are as listed in Appendix A.

With regard to the restriction requirement, Applicants respectively traverse. The requirement imposed by the Examiner limits the subject matter of the invention to a single peptide, with the exception of groups 12, 25, 38, 50, 62, 74, 155, 168, 180 and 192. Claim 1, for example, recites fourteen peptides. It has long been held that the Office may not impose a restriction requirement within a single claim. See *In re Watkinson,* 14 USPQ.2d 1407 (Fed. Cir. 1990) *citing In re Weber*, 198 USPQ 328, 332 (CCPA 1978) and *In re Haas,* 198 USPQ 334, 336 (CCPA 1978). The courts have definitively ruled that the statute authorizing restriction practice (i.e. 35 U.S.C. § 121), provides no authority to impose a restriction requirement within a single claim, even if the claim presents multiple independently patentable inventions. In these cases, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Office to fashion such a rejection. As noted in *In re Weber*:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim, no matter how broad, which means no matter how many independently patentable inventions may fall within it.

In re Weber at 334.

Alleging that a particular claim represents multiple "patentably distinct" inventions is a *de facto* rejection of the patentability of the claim because the claim cannot issue as drafted. In this regard the courts have noted:

> As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not effect the rights of the applicant eventually to have each of the claims examined in the

> form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim will never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than the applicant, it is not inconceivable that a number of fragments would not be described in the specification.

See In re Weber, supra, emphasis added.

In addition, the restriction requirement imposes a burden on the applicant, requiring the filing of over 190 applications in order to pursue all disclosed subject matter. Here, it should be clear that the exorbitant costs of filing this number of patent applications does not strike an appropriate balance between the administrative concerns of the Office and the applicants' statutory rights as inventors. For the foregoing reasons, Applicants respectfully request withdrawal of the restriction requirement.

Should the Examiner not find the traversal persuasive, in order to be fully responsive, Applicants elect the subject matter of group 12, consisting of claims 1(in-part), 2 and 5, directed to SEQ ID NOS: 97-99, with traverse and without prejudice to the prosecution of the subject matter of non-elected claims in other patent applications.

Furthermore, Applicants respectfully request that the Examiner consider examination of additional groups related to the peptides recited in group 12. Groups 25 (peptide-cargo complexes) and 38 (expression cassettes) are not distinct from group 12. Applicants submit that the subject matter of group 12 is a subcombination of the subject matter of groups 25 and 38.

> To support a requirement for restriction, both a two way distinctness and reasons for insisting on restriction are necessary. The inventions are distinct if it can be shown that the combination as claimed: (a) does not require the particulars of the subcombination as claimed for patentibility and (b) the

> subcombination can be shown to have either utility by itself or in other and different relations.

See MPEP 806.05(c).

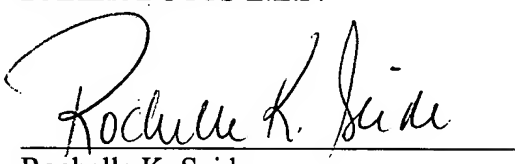
Applicants submit that the combinations of peptide-cargo (group 25) and expression cassette (group 38) require the subcombination of peptide as the essential distinguishing feature of the combination. The inventions are not distinct and a requirement for restriction is improper. Therefore, Applicants respectfully request that the Examiner consider the examination of the inventions of groups 25 and 38 in the present invention.

With regard to groups 50, 62, 74, 155, 168, 180 and 192, Applicants submit that these groups are related to group 25 (product) as processes of using the product. In the parent application, United States Patent Application Serial No. 09/ 653,182, a restriction requirement similar to the present application was imposed. The Examiner rejoined one method of using elected peptides to the application in the Office Communication mailed June 25, 2003. Therefore, Applicants respectfully request the Examiner consider the examination of the inventions of groups 50, 62, 74, 155, 168, 180 and 192 in the present application.

Applicants enclose herewith the fee required for a one month extension of time. Applicants believe that no additional fees are required in connection with this communication. However, if any additional fee is required in connection with this communication, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 02-4377. A duplicate copy of this page is included herewith.

Respectfully submitted,

BAKER BOTTS L.L.P.



Rochelle K. Seide
PTO Reg. No. 32,300

Carmella L. Stephens
PTO Reg. No. 41,328

Attorneys for Applicants

Dana Lau
PTO Reg. No. 55,361
Agent for Applicants

30 Rockefeller Plaza
New York, NY 10112-4498
(212) 408-2626